SMi present their cutting edge Conference on...

Adaptive Designs in Clinical Drug Development - Scope, Implementation & Case Studies

5th & 6th February 2007, Crowne Plaza - The City, London

To attend, contact Benn Walsh on Tel +44 (0) 20 7827 6158, Fax +44 (0) 20 7827 6159, email bwalsh@smi-online.co.uk or visit www.smi-online.co.uk/ts02.asp to register online

“This (conference) is one of the best!”
Dr Inna Prevozskaya, Senior Biometrician, Clinical Biostatistics, Merck Research Laboratories
Speaker: SMi’s Inaugural conference Innovating Clinical Drug Development – A Focus on Biostatistics for Clinical Drug Design 2006
8.30 Registration & Coffee

9.00 Joint Chairpersons' Opening Remarks
Dr Michael Krams, aVP, Adaptive Trials, Clinical Development, Wyeth

Dr Jerald Schindler, President, Cytel Pharmaceutical Research

ADAPTIVE DESIGNS - THE ANSWER TO DEVELOPMENT PROBLEMS?

ADAPTIVE DESIGNS - TAXONOMY AND CLASSIFICATION

9.10 Setting the scene

• Providing a common denominator for terminology
• Defining what is in and out of scope
• Proposing where to focus our efforts
• Giving some key examples, case studies and/or simulations

Dr Inna Perevozskaya, Senior Biometrician, Clinical Biostatistics, Merck Research Laboratories*

ISSUES IN IMPLEMENTING ADAPTIVE TRIALS

9.50 Ensuring that there are no blockages to implementation

• Ethical issues
• Complications in design and implementation
• Increasing awareness of adaptive designs
• Reducing biases
• Behavioural problems
• Is the market ready to fully embrace adaptive clinical trials?

Dr Steve Pascoe, Global Head, Respiratory/Dermatology Profiling Exploratory Clinical Development, Novartis

10.30 Morning Coffee

REGULATORY ACCEPTANCE OF FLEXIBLE DESIGNS

11.00 Current regulatory landscape - EMEA, FDA, MHRA

• EMEA reflection paper on flexible designs
• Opportunities and challenges from a regulatory perspective
• Building a new approach to very early interactions between sponsor and health authority

Dr Ian Hirsch, Statistics, Medicines & Healthcare products Regulatory Agency (Mhra)

ARE WE READY TO DEPLOY?

ADAPTIVE TRIAL DESIGN INFRASTRUCTURE

11.40 Acquiring data early and linking with drug supply

• Key issues in operation for effective clinical trial
• Optimisation of clinical trials infrastructure
• Infrastructure needed to incorporate flexibility into trial design
• Providing rapid access to ongoing trial information
• Building the infrastructure
• Design, process and planning

Dr Jerald Schindler, President, Cytel Pharmaceutical Research

MODEL-BASED ADAPTIVE DESIGNS

1.50 A working model for dose-response relationship

• Proposing a general class of adaptive designs based on optimal experimental design methodology
• Estimation of the target dose as accurately as possible
• Ethical concerns - ensuring the treatment of patients in the study are at doses that are both safe and efficacious

Dr Vlad Dragalin, Senior Director, Research Statistics, GlaxoSmithKline

IMPLEMENTATION - GETTING IT RIGHT BEFORE PHASE III

2.30 Dose adaptive phase I and phase II trials

• Simulation guided trial design:
  - What's the question?
  - Optimising the design
• Running dose adaptive studies

Tom Parke, Associate Director, Software Development, Tessella Support Services

3.10 Afternoon Tea

SAMPLE SIZE REASSESSMENT - GOOD OR BAD?

3.40 The need for and logical difficulties with flexible designs

• Many recent papers promote flexible designs that allow substantial design modifications
• The type I error can be protected by using a weighted test
• However, the efficiency of these designs has been questioned
• We also show that the weighted test can lead to absurd conclusions
• What can be done to combine flexibility with a convincing inference?

Dr Carl-Fredrik Burman, Statistical Science Director, Cytel Pharmaceutical Research

NEW AREAS FOR CONSIDERATION

4.20 INTERACTIVE ROUNDTABLES

• There will be three areas of discussion:
  - PHASE I: Identify the MTD
  - SEAMLESS PHASE II/III
  - PHASE II: Adaptive dose response finding
• What is the research question?
• What and how will we adapt?

Participants will design their own adaptive trial, by applying the material covered to a research question from their own experiences.

Groups will be limited to approximately six participants and will be led by one or two members of the faculty. The session will close with each group briefly presenting their design and issues they encountered to the full group.

5.30 Joint Chairpersons' Closing Remarks and Close of Day One

*Awaiting final Confirmation
Day Two
6th February 2007

9.00 Joint Chairpersons’ Opening Remarks
Dr Michael Krams, aVP, Adaptive Trials, Clinical Development, Wyeth
Dr Jerald Schindler, President, Cytel Pharmaceutical Research

9.10 Selecting the right one?
- Treatment (dose) selection
- Adaptive designs and the closed test principle
- Sample size reassessment
- Seamless phase II/III designs
Dr Franz Koenig, University Assistant, Section of Medical Statistics, Medical University of Vienna

9.50 SEAMLESS PHASE II/III AND SAMPLE SIZE REESTIMATION IN PHASE III – CASE STUDIES
Dr Michael Krams, aVP, Adaptive Trials, Clinical Development, Wyeth

10.30 Morning Coffee

10.50 Application of Adaptive Design in Vaccine Development
With examples in:
- Sample size re-estimation
- Group sequential design
- Group sequential adjusted estimation
- Software implementation
Dr William Wang, Associate Director, Clinical Biostatistics, Merck & Co

11.30 Assessing safety in the drug development process
- Designs and statistical methods to assist in making decisions
- Streamlining the drug development process
- Reducing the risk of late stage clinical failure
- Lowering development costs
Dr Jerry Weaver, Associate Director, Pfizer

12.00 Joint Chairpersons’ Closing Remarks and Close of Conference

2.20 Use of Bayesian methods in design
- Opportunities and challenges
- Development in Bayesian methods
- Application of Bayesian methods in a novel product
- Practical Examples
The challenges of the Bayesian approach in the regulatory setting
Dr Junfang Li, Director, Biostatistics, Sanofi-Aventis

3.00 Approaches to clinical development
- Key points for the Bayesian approach to clinical trials
- Use of Bayesian methods in support of decision-making in clinical development
- Providing a practical point of view
- Producing a checklist of essential items needed
Beat Neuenschwander, Senior Expert, Statistical Methodologist, Novartis

3.40 Afternoon Tea

4.00 Applications of beat-to-beat in QT-TQ interval data
- Methods for multivariate reference regions
- Moving beyond QT prolongation using beat-to-beat QT-TQ data
- QT-TQ reference region for a normal individual
Dr Kimberly Crimin, Senior Principal Biostatistician II, Wyeth
Co-authored by Dr Robb Muirhead, Senior Director, Pfizer

4.40 Issues in implementation
- Where are we?
- Where do we want to be?
- Next steps - how are we going to get there?

By focusing on the strategic and analytical issues in implementing adaptive designs, members of the faculty and audience are invited to participate in this panel discussion.

5.20 Joint Chairpersons’ Closing Remarks and Close of Conference

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Events bring together senior industry professionals and serving companies who have a focus on being at the forefront of developments in this area. SMi aim to generate informed and topical discussion through the medium of both Conferences and Executive Briefings.

Our Pharmaceutical events are research-based and content driven with regular contact with major industry personnel and cover a wide range of industry sectors. For more information please visit www.smi-online.co.uk/pharma.asp

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23/24 Medical Devices - Regulation, Clinical Evaluation & Post Market Surveillance
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01/02 HIV & AIDS - Novel Therapeutics and Strategies to Beat the Pandemic
01/02 European Pharmaceutical Pricing & Reimbursement, Frankfurt, Germany
13/14 Clinical Trials in CNS
20/21 Advances in Anti-Inflammatory Therapeutics
29/30 Outsourcing Clinical Trials

JANUARY 2007
22/23 Practical Approaches to Cardiac Safety
24/25 Paediatric Clinical Trials
31/1 Therapeutic Antibodies

FEBRUARY 2007
5/6 Adaptive Designs in Clinical Development - Scope, Implementation and Case Studies
7/8 Imaging in Neurology
12/13 Optimising Drug Formulation
14/15 Parallel Trade
21/22 Pharmaceutical Packaging & Labelling 2007
28/1 Drug Design VI

Introduction to Adaptive Designs - Concepts & Issues

7th February 2007, Crowne Plaza - The City, Central London

In association with:

About the Executive Briefing:
This briefing will introduce the basic statistical theory of group sequential tests and some fundamental concepts of the adaptive design technique. Planning issues as well as how to analyse a trial with adaptive multistage group sequential test designs will be described.

8.30 Registration and Coffee
9.00 Group sequential designs
• Basics
• Critical values
• Types of common designs
• Power and sample size
• Comparison of designs
• Where are the merits?
9.45 The use function approach and other issues
• Definition
• Design characteristics
• Applications
• P-values and confidence intervals
• Practical issues
10.30 Morning Coffee
10.45 Adaptive designs
• The concept
• Two basic strategies
• Adaptive designs as a generalisation of group sequential designs
• Planning and analysis tools
11.30 Practical implementation of adaptive designs
• Specific issues
• Software solutions for group sequential and adaptive designs
• Practical examples
• The EMEA guideline
• Where do we go?
12.15 Discussion and questions - review of the session
12.30 Close of Executive Briefing

About the Briefing Leader:

Gernot Wassmer, PhD, is an Associate Professor for Biostatistics at the Institute of Medical Statistics, University of Cologne, Germany. He received his PhD 1993 at the University of Munich, Germany. From 1993 – 2000 he was a Research Fellow at the Institute of Statistics, University of Munich, at the Institute for Epidemiology, GSF Neuherberg, and at the Institute of Medical Statistics, University of Cologne. He also works as a statistical consultant for the pharmaceutical industry. His major research interest is in the field of statistical procedures for group sequential and adaptive plans in clinical trials.

About the Organisation:
The University of Cologne is a research university at the highest level with more than 250 co-operating institutes and departments. The Institute for Medical Statistics, Informatics and Epidemiology offers research, teachings, services and consultancy with special emphasis on biometrical research and its application in clinical trials.
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ADAPTIVE DESIGNS IN CLINICAL DRUG DEVELOPMENT
5th & 6th February 2007, Central London

EXECUTIVE BRIEFING
7th February 2007, Central London

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